



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Keith D. ALLEN *et al.*

Serial No.: 10/005,921

Filed: December 4, 2001

Title: Transgenic Mice Containing CASH Gene Disruptions

Group Art Unit: **1632**

Examiner: **Paras Jr., Peter**

Customer No. **26619**

Docket/Order No. **R-714**

Date: **September 11, 2003**

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Mail Stop Non-Fee Amendments
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed August 14, 2003 concerning the Examiner's restriction to the claims in connection with the above-referenced application, Applicants elect without traverse Group III (claims 8, 10 and 14-21), drawn to a transgenic non-human animal, particularly a mouse comprising a disruption in a CASH gene, a method of making the same, and methods of using the same to identify potentially therapeutic agents. It is believed that no fees are due associated with the instant response. However, the Commissioner is hereby authorized to charge any deficiency in payment to Deposit Account No. 50-1271 under Order No. R-714.

Respectfully submitted,

Date: 9/11/03

Kelly Quast

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a targeting construct comprising nucleotide sequences homologous to a CASH gene and a method of producing a targeting construct, classified in class 435, subclass 320.1.
- II. Claims 5-7 and 9, drawn to cells comprising a disruption in a CASH gene, classified in class 435, subclass 325.
- III. Claims 8, 10, 14-21, drawn to a transgenic non-human animal, particularly a mouse comprising a disruption in a CASH gene, a method of making the same, and methods of using the same to identify potentially therapeutic agents, classified in classes 800, 800, and 800 subclass 13, 18, and 25.
- IV. Claims 11, drawn to methods of identifying agents that modulate the expression of a CASH gene or modulate the function of a CASH comprising screening said agents in a transgenic non-human animal, classified in class 800, subclass 3.
- V. Claims 12, drawn to methods of identifying agents that modulate expression of a CASH gene or function of a CASH in a cell *in vitro*, classified in class 435, subclass 7.2.
- VI. Claims 13 and 24, drawn to an unknown agent is unclassifiable.

- VII. Claims 22-23, drawn to a method of identifying an agent that modulates a phenotype associated with or behavior associated with a disruption in a CASH gene, comprising screening agents in a transgenic mouse, classified in class 800, subclass 3.
- VIII. Claim 25, drawn to a method of treating pain, comprising administering CASH, classified in class 424, subclass 184.1.
- IX. Claim 26, drawn to a method of treating seizures, comprising administering CASH, classified in class 424, subclass 184.1.

Claim 27 link(s) inventions VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The products of Inventions I, II, III, and VI are distinct each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of Groups I, II, III, and VI have different chemical structures, are made by different methods, and can be used in different methods which require different technical considerations and materially different reagents. For example, the transgenic animal non-human animal of Group III can be used as a model of disease while the targeting construct of Group I may be used to disrupt a gene in a somatic cell *in vitro*, and the cells of Group II may be used to isolate a protein. Also, the agent of group VI has a different chemical structure from the targeting construct, cells, and transgenic non-human animals of Groups I, II, and III respectively, and may be used in different methods, which require different technical considerations with respect to modulation of a CASH. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups IV, V, VII, VIII and IX because their methods appear to constitute patentably distinct inventions, each with a distinct purpose

and further comprising distinct methodologies and using different products. For example, the method of Group IV requires the use of a transgenic non-human animal to identify agents that modulate expression or function of CASH while the method of Group V requires the use of a cell *in vitro* to identify agents that modulate expression or function of CASH and the method of Group VII is directed to identifying agents that modulate a phenotype of a transgenic mouse comprising a disruption in a CASH gene. The methods of Groups VIII and IX differ from the methods of Groups IV, V, and VII, in that they are treatment methods requiring administration of CASH. Groups VIII and IX differ each from the other as they are directed to treating different disorders, pain and seizures, respectively. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups IV, V, VII, VIII and IX restriction for examination purposes as indicated is proper.

The products of Inventions I, II, III, and VI and the methods of Inventions IV, V, VII, VIII and IX are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects each from the other. The products of Groups I, II, III, and VI can be used in methods that require different technical considerations and materially different reagents from the methods of Groups IV, V, VII, VIII, and IX. The methods of Groups IV, V, VII, VIII and IX can be practiced with products that have different chemical structures than the products of Groups I, II, III, and VI. For example, the transgenic

animals of Group II may be used to produce antibodies while the methods of Groups IV and V may be used to identify agents that modulate the expression of a CASH and the methods of Groups VII and VIII may be used for treatment of pain or seizures, respectively. Further, the methods of Groups IV and V may be practiced with agents that have different chemical structures from the agents of Group VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

PETER PARAS
PATENT EXAMINER

Art Unit 1632

